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10/537,412	06/02/2005	Stuart Alan McNeill	CAF-201-A	1464

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EXAMINER	
LLOYD, EMILY M	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,412	MCNEILL ET AL.	
	Examiner	Art Unit	
	EMILY M. LLOYD	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2008 and 28 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 July 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to Applicant's 2 July 2008 amendment. The Examiner acknowledges the amendments to claims 1-21 as well as the abstract and specification, and the drawing replacement sheets 1/5 and 5/5. Currently, claims 1-21 are pending.

2. The Examiner notes that Applicant's specification amendments refer to paragraph numbers which were not provided in the specification submitted on 2 June 2005. It appears that the Applicant referenced the paragraph numbers from the Patent Publication for this application (US 2006/0051734 A1). Confirmation of this is requested with Applicant's next response.

Specification

3. The disclosure is objected to because of the following informalities: page 14 lines 27 and 29 the period after the figure numbers (4 and 5) should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 10, it is unclear if the piezoelectric device as claimed is an actuator, a transducer, or another element. For the purpose of examination, the

Examiner has interpreted the piezoelectric device in claim 10 as a piezoelectric actuator. Further, it is unclear how strain is monitored with a stress sensor.

Regarding claim 12, it is unclear if the signal is used to control the position of the actuator or is possibly used for monitoring displacement of the periodically displaceable body.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A signal is non-statutory subject matter as it is not a process, machine, manufacture, or composition of matter. Amending "is controlled whereby a signal of the position of said actuator" to "is configured to be controlled by a signal of the position of said actuator" will overcome this rejection.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-9 and 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent Publication 2005/0256387 (Omata).

Regarding claim 1, Omata discloses an apparatus suitable for use in investigating multi-phase biological tissue histology (Figure 7), comprising: a trans-ductally deployable probe (Figure 7 and claim 5 "a probe base for being inserted into the canal part of the human body") mounted on a periodically displaceable body (probe 7 Figure 7 and claims 5 and 6) of at least one tactile sensing device (vibration detector 45 Figure 7); a displacement device (vibration element 43 Figure 7) having a displacement controller (phase shift circuit 55 Figure 7, [0048] and [0049]) configured to control at least said excitation frequency of the periodically displaceable body ([0048] and [0049]); and a displacement monitoring device (deviation detection sensor claim 5)

and a displacement force monitoring device (hardness sensor claim 5, hardness is measured with a ratio of measured force over a measured area to a reference force over a reference area, so a hardness sensor would have to measure force over area, which inherently measures force), both coupled to the periodically displaceable body and configured to monitor a viscoelastic response of said biological tissue to periodic compression by said displacement force applied to said tissue by periodic displacement of said periodically displaceable body (claims 5 and 6).

Omata does not expressly disclose that the periodically displaceable body has an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N because Applicant has not disclosed that these measurements provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Omata's elasticity measuring device, and applicant's invention, to perform equally well with either the disclosure of Omata or the claimed frequency, stroke length, and displacement force because the claimed frequency, stroke length, and displacement force would perform the same function of applying a safe yet effective motion to a body canal equally well considering the typical material properties and sizes of body canals.

Therefore, it would have been prima facie obvious to modify Omata to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Omata.

Regarding claim 2, Omata teaches the apparatus according to claim 1 wherein said probe is configured to be trans-ductally deployable in at least one of a genito-urinary tract in males and females, a gastro-intestinal tract, a respiratory tract, and within an arterial and venous vasculature system (Figure 7 is capable of fitting in the gastro-intestinal tract, also claim 5 “inserted into a canal part of a human body").

Regarding claim 3, Omata teaches the apparatus according to claim 1 wherein said probe, when used for trans-urethral deployment, has a diameter of not more than 5 mm ([0037] lines 7-8, with the sleeve 9 covering the distal end the invention would only be slightly larger than probe base 5).

Regarding claim 4, Omata teaches an apparatus according to claim 3 wherein said probe has a length of from 1 to 3 cm (probe 7 Figure 7 would be in this range given the probe diameter).

Regarding claim 5, Omata teaches the apparatus according to claim 1 wherein said periodically displaceable body is actuated via at least one of: a pressurized fluid circuit, a mechanical drive system, and a piezoelectric actuator (micro-motor [0039] lines 17-19 is a mechanical drive system).

Regarding claim 6, Omata teaches the apparatus according to claim 1 wherein said probe is mounted at the distal end of an elongate deployment device ([0037] lines 3-7).

Regarding claim 7, Omata teaches the apparatus according to claim 6 wherein said periodically displaceable body is actuated by a proximally mounted motor ([0039] lines 17-19).

Regarding claim 8, Omata teaches the apparatus according to claim 6 wherein said periodically displaceable body is actuated by a distally mounted motor drivingly connected to the displaceable body via said elongate deployment device ([0039] lines 17-19).

Regarding claim 9, Omata teaches the apparatus according to claim 1 wherein said periodically displaceable body comprises at least one micro-piston actuated via a pressurized fluid circuit (stress detection sensor 21 Figure 3, also claim 7).

Regarding claim 11, Omata teaches the apparatus according to claim 1 wherein the periodically displaceable body has a force-transmitting surface and is configured such that an area of the surface and a magnitude of the force applied by the periodically displaceable body is user-adjustable ([0039] lines 17-19 the length and speed of the movement of sleeve 9 and probe base 5 relative to each other would determine the area of the surface applied to the tissue and the magnitude of the force).

Regarding claim 12, Omata teaches the apparatus according to claim 1 wherein said displacement device incorporates an actuator whose position is controlled (micro-motor [0039] lines 17-19), wherein a signal of the position of said actuator may be used

to monitor displacement of the periodically displaceable body ([0039] lines 10-19 clearly knowing the position of the actuator discloses the position of probe 7 and therefore contact ball 19).

Regarding claim 13, Omata teaches the apparatus according to claim 1 wherein a force detector is incorporated in at least one of the displacement controller, the displacement device, and the periodically displaceable body (stress detection sensor 21 in displaceable body/contact ball 19 Figure 1).

Regarding claim 14, Omata teaches the apparatus according to claim 1 wherein the displacement controller is configured to operate the periodically displaceable body at a plurality of different excitation frequencies ([0039] lines 17-22).

Regarding claim 15, Omata teaches the apparatus according to claim 1 wherein the displacement controller is configured to control each of said excitation frequency and stroke length (micro-motor [0039] lines 17-19 inherently has a controller).

Regarding claim 16, Omata teaches the apparatus according to claim 1, further comprising: a position control device configured to change the position of the periodically displaceable body within a body duct, during use of the apparatus, so as to successively bring the periodically displaceable body into contact with a plurality of different duct surface portions (Figure 6).

Regarding claim 17, Omata teaches the apparatus according to claim 1 further comprising: a processing unit configured to process displacement and displacement force data (elasticity calculation device 29 Figure 1) so as to generate at least one of dynamic modulus and Amplitude Ratio (Figure 6 essentially shows an Amplitude ratio;

Force plotted versus time produces the same curve as Stress versus time for the force being applied to a known area; Displacement versus time (where displacement and force are 0 at an initial time) represents strain over time; and plotting force/stress versus displacement/strain provides a ratio of stress to strain for a specific stress or strain).

Regarding claim 18, Omata discloses a method for producing a histological profile of a biological tissue adjacent a duct comprising the steps of: a) providing an apparatus according to claim 1 (Figure 7; see rejection of claim 1 above); b) transductally inserting the probe of said apparatus to bring the periodically displaceable body of said probe into contact with a ductal surface of said biological tissue at a plurality of positions across said ductal surface (Figure 6); c) subjecting said periodically displaceable body to a periodic displacement thereby periodically compressing said biological tissue at said contact positions across said ductal surface ([0048], [0049], and claims 5 an 6); d) monitoring the viscoelastic response of said tissue at each of said contact tissue positions to the compressing by said periodically displaceable body (Figure 6, [0048], [0049], and claims 5 an 6); and e) generating a profile of the viscoelastic response of the tissue across said ductal surface (Figure 6, [0048], [0049], and claims 5 an 6).

Omata does not expressly disclose that the periodically displaceable body has an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an excitation frequency

bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N because Applicant has not disclosed that these measurements provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Omata's elasticity measuring device, and applicant's invention, to perform equally well with either the disclosure of Omata or the claimed frequency, stroke length, and displacement force because the claimed frequency, stroke length, and displacement force would perform the same function of applying a safe yet effective motion to a body canal equally well considering the typical material properties and sizes of body canals.

Therefore, it would have been prima facie obvious to modify Omata to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Omata.

Regarding claim 19, Omata teaches the method as claimed in claim 18 further comprising a preliminary step of: determining values of displacement frequency, displacement stroke length and displacement force suitable for histological profiling of a type of biological tissue to be profiled (it is well known in the art to adjust devices to the size and health of the patient, as well as the part of the patient that is being examined; for example, otoscopes come with different attachments for different size ears and noses).

Regarding claim 20, Omata teaches the method according to claim 18, wherein said plurality of tissue surface contact positions are distributed axially and/or circumferentially of said duct ([0038] lines 20-21).

Regarding claim 21, Omata discloses a method of diagnosing a condition manifested by a histological abnormality in biological tissue adjacent a body duct comprising the steps of: a) providing an apparatus according to claim 1 (Figure 7; see rejection of claim 1 above); b) trans-ductally inserting the probe of said apparatus to bring the periodically displaceable body of said probe into contact with a ductal surface of said biological tissue at successive ones of a plurality of positions across said ductal surface (Figure 6); c) subjecting said periodically displaceable body to a periodic displacement thereby periodically compressing said biological tissue at said contact positions across said ductal surface ([0048], [0049], and claims 5 an 6); d) monitoring the viscoelastic response of said tissue at each of said tissue contact positions to the compressing by said periodically displaceable body (Figure 6, [0048], [0049], and claims 5 an 6); e) generating a profile of the viscoelastic response of the tissue across said ductal surface (Figure 6, [0048], [0049], and claims 5 an 6); and f) comparing said generated viscoelastic response profile with viscoelastic response profiles of such tissue having known histological characteristics ([0005] and [0006]; [0005] discusses the lack of measurement of elasticity and the lack of “determination of degree of elasticity deterioration” in the prior art; a determination of degree is based on comparison to pre-existing measurements or standards for various characteristics; [0006] says Omata’s invention intends to overcome these limitations of the prior art; as Omata discloses

viscoelastic response profiles as a measurement of elasticity, Omata suggests comparing his measurements, or viscoelastic response profiles, to determine the degree of deterioration, and deterioration is an abnormality; determining a degree of deterioration is thus diagnosing a condition that is associated with the abnormality).

Omata does not expressly disclose that the periodically displaceable body has an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N because Applicant has not disclosed that these measurements provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Omata's elasticity measuring device, and applicant's invention, to perform equally well with either the disclosure of Omata or the claimed frequency, stroke length, and displacement force because the claimed frequency, stroke length, and displacement force would perform the same function of applying a safe yet effective motion to a body canal equally well considering the typical material properties and sizes of body canals.

Therefore, it would have been prima facie obvious to modify Omata to obtain the invention as specified in claim 1 because such a modification would have been

considered a mere design consideration which fails to patentably distinguish over the prior art of Omata.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Omata as applied to claims 1-9 and 11-21 above, and further in view of United States Patent 5779651 (Buschmann et al.).

Regarding claim 10, Omata discloses an apparatus according to claim 1 wherein said periodically displaceable body comprises: at least one shoe (contact ball 19); an actuator device mounted on each of the at least one shoe (probe 7 and sleeve 9); and a stress detector element sandwiching the actuator device against the at least one shoe (stress detection sensor 21), the stress detector element configured to monitor strain on the actuator device and determine the force applied by said periodically displaceable body to the biological tissue (Omata teaches stress detection sensor 21 adjacent contact ball 19 of a known surface area; a stress detection sensor with a known area is equivalent to a force sensor).

Omata discloses the claimed invention except for the use of a piezoelectric actuator. Buschmann et al. teach that actuators can be electromechanical, piezoelectric, or manual (Column 5 lines 11-14). It would have been obvious to one having ordinary skill in the art to replace the electromechanical and manual actuators taught by Omata with a piezoelectric actuator as taught by Buschmann et al. as this substituting equivalents (actuators) known for the same purpose (of actuating a device) (see MPEP 2144.06 II).

Response to Arguments

12. Applicant's arguments filed 2 July 2008 have been fully considered but they are not persuasive.

13. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., calculation of the complex dynamic modulus, sinusoidal strain, differentiating between benign and malignant tissue) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

14. Regarding Applicant's arguments regarding the design choice rejections with the Omata reference, the Applicant has not proven that the particular ranges of excitation frequency, maximum stroke length, and displacement force in the claims provide an advantage, are used for a particular purpose, or solve a stated problem. Further, Applicant's reference to [0022] supports a design choice rejection, as it does not state any of the numerical values claimed and instead says "The range of suitable displacement frequency, displacement stroke length and displacement force for each type of tissue may be readily determined experimentally" ([0022] of US 2006/0051734 A1). The description of the values being "readily determined experimentally" indicates that routine experimentation with the device of Omata (which anticipates all but the claimed ranges) would result in Applicant's claimed invention. See also MPEP 2144.05 II.

15. Regarding Applicant's arguments that Omata does not teach diagnosis as required by claim 21, the Examiner disagrees. Omata [0005] discusses the lack of measurement of elasticity and the lack of "determination of degree of elasticity deterioration" in the prior art. A determination of degree is based on comparison to pre-existing measurements or standards for various characteristics. Omata [0006] says Omata's invention intends to overcome these limitations of the prior art. As Omata discloses viscoelastic response profiles as a measurement of elasticity, Omata suggests comparing his measurements, or viscoelastic response profiles, to determine the degree of deterioration. Deterioration of tissue is an abnormality. Determining the degree of deterioration is thus diagnosing a condition that is associated with the abnormality.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
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/EML/

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